

Glide Path Enlargement of Curved Molar Canals Using HyFlex EDM Glide Path File versus PathFile: A Comparative Study of Preparation Time and Postoperative Pain

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Research article

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Abstract

Background: This randomized clinical trial aimed to compare the preparation time and severity of postoperative pain between the HyFlex Electric Discharge Machine (EDM) Glide Path File (GPF) and PathFile.

Methods: Eighty patients whose molar teeth had at least one severely curved canal were treated by the same specialist. After access cavity preparation, the patients were randomly assigned to receive glide path enlargement with either HyFlex EDM GPF or PathFile. ProTaper Next X1 and X2 files were used to prepare the canals. The time of preparation was assessed and the severity of postoperative pain over the next 7 days was recorded. The preparation time and the postoperative pain scores were compared using one-way analysis of variance (ANOVA) ($P \leq 0.05$).

Results: Glide path enlargement time was significantly shorter with HyFlex EDM GPF (27.828 ± 2.345 sec) than with PathFile (48.942 ± 2.864 sec) ($P < 0.001$). The highest postoperative pain score was recorded on the first day and the pain decreased over time in both groups. HyFlex EDM GPF group patients reported significantly less postoperative pain than PathFile group patients overall ($P < 0.05$).

Conclusion: Postoperative pain and glide path preparation time could be reduced by using the HyFlex EDM GPF system.

Trial registration: PKUSSNCT, PKUSSNCT-17B12, Registered 24 October 2017

Background

Endodontic postoperative pain is a sensation of discomfort experienced by 25%–40% of patients after root canal treatment [1, 2]. Post-endodontic pain usually occurs during the first 2 days after treatment and generally diminishes within a few hours. However, in some cases, the pain may persist for several days. Multiple factors contribute to the pain sensation and severity. Clinical investigation of the postoperative pain is challenging [3]. Mechanical, chemical, and microbiological injuries to periapical tissues are regarded as the main causes of acute periapical inflammation [4]. Irritants such as infected debris extruded into the periradicular tissues during root canal preparation may induce the acute-inflammatory response. Extruded debris can also cause different levels of postoperative pain, and to date, all root canal preparation instruments and techniques have been associated with some degree of debris extrusion [5,6]. Procedural steps such as glide path preparation and the establishment of apical patency as well as the root canal instrumentation technique are important factors that influence and reduce the post-treatment pain incidence [3, 7, 8, 9].

The endodontic glide path is the smooth tunnel created from the orifice of the root canal to the physiological terminus of the root apex, which facilitates cleaning and shaping during root canal treatment [10]. Preliminary canal enlargement is also considered an important step as it can reduce torsional stress, and further, increases the life span of the shaping instruments. This also reduces the risk

of procedural errors such as ledge formation, canal transportation, and perforations [11, 12]. Glide path enlargement can be performed with precurved stainless steel K-files or nickel–titanium (NiTi) glide path files (GPFs). In 2017, Alovisei et al and Paleker et al demonstrated that NiTi rotary instruments enable faster and safer preparation of a glide path that respects the original canal anatomy [13, 14].

The HyFlex EDM (Coltene/Whaledent, Altstätten, Switzerland) NiTi GPF is a GPF file system produced using an innovative manufacturing process called Electrical Discharge Machine with a controlled memory (CM) wire. In EDM, instead of conventional grinding, electric discharges are used to shape the file via melting and vaporization of the material [15]. This method creates a cratered surface, which further increases the file's cyclic fatigue resistance and lifetime [16]. The HyFlex EDM GPF consists of a single file with a tip size of 10 and a 5% taper. The cross-section of the HyFlex EDM GPF varies along its length, being quadratic at the tip, trapezoidal in the middle, and triangular at the shaft. The flexibility of the HyFlex EDM GPF confers this instrument the ability to maintain the apical canal curvature despite its greater taper [17].

The PathFile (Dentsply Sirona, Ballaigues, Switzerland) NiTi rotary system consists of three file systems, which are made of conventional NiTi alloy with different tip sizes such as 13#, 16#, and 19#. The files have square cross-sections, with four cutting edges and a 2% taper. Glide path preparation with PathFile promotes less deviation from the original canal anatomy when compared with hand-operated instruments [18].

The effect of GPFs on postoperative pain has not been adequately investigated. Therefore, the aim of this study was to compare the preparation time and severity of postoperative pain with two glide path preparation systems—HyFlex EDM GPF versus PathFile.

Methods

The study was approved by the local university clinical research ethics committee with vide letter no. PKUSSIRB-201735063. Using the PASS software, the required sample size in this study was determined by comparing the mean preparation time for HyFlex EDM GPF and PathFile. In this study, a bilateral test was used, with a test level of 0.05 and a power of 90%. Informed consent was obtained from the patients before enrollment in the study.

The sample consisted of 80 patients aged 23-73 years old who were treated at the Second Dental Center of Peking University School of Stomatology between June 2018 and February 2019. All participants were informed about the study and had provided written informed consent prior to treatment. The following inclusion criteria had to be fulfilled by the patients to be enrolled in the study: 1) No previous history of systemic diseases. 2) Selected for root canal treatment for asymptomatic or symptomatic irreversible pulpitis in the maxillary or mandibular molars with at least one severely curved canal ($>25^\circ$). The exclusion criteria were 1) pulp necrosis, with or without apical periodontitis. 2) Acute or chronic apical abscess. 3) Signs of systemic infection. 4) Allergic to local anesthetic agents. 5) Progressive periodontal

disease at any stage (clinical attachment loss ≥ 5 mm, probing depth ≥ 6 mm, or furcation involvement class II or III).

Before the procedure, pulpal and periradicular status was evaluated by means of vitality tests such as a cold test, an electric pulp tester (Diagnostic, SybronEndo, USA), palpation, and percussion. Periodontal probing was performed and patients with deep periodontal pockets were excluded. After the administration of local anesthesia with 4% mepivacaine with adrenaline 1:100,000 and isolation of the tooth with a rubber dam, a standard access cavity was prepared using diamond burs. At this stage, a sealed envelope containing the randomization code was opened and the patient was assigned to receive glide path enlargement with either the HyFlex EDM GPF or PathFile, with 40 patients in each group. Patients were blinded regarding the file system utilized. All the patients were treated by an endodontic dentist.

HyFlex EDM GPF group

The working length (WL) was determined using the Root ZX apex locator (SM-DP-ZX, Morita, China) by inserting a size 10 K-file into the root canal up to the apical foramen. The WL was confirmed radiographically and was also repeatedly checked during the treatment procedure. The HyFlex EDM GPF (size 10/0.05) was operated with an endomotor (X-SMART; Dentsply Maillefer, Switzerland) in continuous rotation at a speed of 300 rpm and 1.8 Ncm of torque, according to the manufacturer's instructions. Irrigation with 5.25% NaOCl and 17% EDTA was carried out during the glide path enlargement and the preparation time was recorded from the insertion of the GPF till the completion of the enlargement, including irrigation time during the enlargement. After the instrumentation was completed, the root canal was irrigated with 5 mL of 5.25% NaOCl and 5 mL of 17% EDTA.

PathFile group

The WL was determined as described above in the HyFlex EDM GPF group. The PathFile (size 13/0.02 and 16/0.02) instruments were operated using the same endomotor (X-SMART) at a speed of 300 rpm and 5 Ncm of torque. Irrigation with 5.25% NaOCl and 17% EDTA was carried out during the glide path enlargement and the preparation time was recorded from the insertion of the PathFile 13/0.02 till the completion of the PathFile 16/0.02 enlargement, including the irrigation time during the enlargement and the time required to change files. After enlargement, the root canal was irrigated with 5 mL of 5.25% NaOCl and 5 mL of 17% EDTA.

After glide path creation, subsequent endodontic procedures were standardized as per the protocol. The root canals were then prepared with X1 and X2 instruments by using the ProTaper Next (Dentsply Maillefer, Switzerland) rotary instrumentation system and then irrigated with 5.25% NaOCl and 17% EDTA.

The preparation time of the severely curved canal for the GPFs and ProTaper Next were recorded. Only the times used for active instrumentation such as checking the WL, cleaning the flutes of the instruments,

and irrigation were included. The time taken to change files was not considered. The preparation times were recorded by a nurse and other canals for the same molar were prepared using only the ProTaper Next.

Finally, the prepared root canals were irrigated again with 10 mL of 5.25% NaOCl with a 30-gauge needle syringe and then dried with sterile paper points. Calcium hydroxide [Ca(OH)₂] was placed in the canals, temporary filling was performed, and an appointment was scheduled to complete the subsequent root canal procedure.

All patients were instructed to record postoperative pain intensity twice daily (morning and evening) for 1 week using a visual analog scale (VAS) on paper. The pain score was recorded on a scale of 0 to 10. Pain intensity was categorized as no pain (0), mild pain (1–3), moderate pain (4–6), and severe pain (7–10). All patients returned the original copies of the VAS form on the next visit.

Statistical analysis

SPSS version 20.0 (IBM Corp., Armonk, NY, USA) was used for statistical analysis. The distributions of age, sex, the tooth treated, and the angle of root canal curvature in the two treatment groups were compared by using the chi-square test. The preparation time and the postoperative pain scores were compared using one-way analysis of variance (ANOVA). Statistical significance was recognized at $P \leq 0.05$ (two-sided). Considering that multiple pain measurements were performed for the same individual within 7 days after the preparation of the curved root canal, the repeated measurement ANOVA model was used to analyze the differences between groups and the trend of pain changes over time in different groups.

Results

The age of the patients in the HyFlex EDM GPF group was 48.1 ± 14.1 (12 men and 28 women) compared to 45.5 ± 14.4 (11 men and 29 women) in the PathFile group. Regarding the tooth type, 19 first molars and 21 second molars were included in each group. The angle of the root canal was $28.8^\circ \pm 6.8^\circ$ in the HyFlex EDM GPF group and $26.5^\circ \pm 8.3^\circ$ in the PathFile group. Demographic variables such as age and sex and clinical variables such as the tooth type and the angle of the root canal curvature were similarly distributed in the two treatment groups (all $P > 0.05$; Table 1).

Table 2 presents the mean total times for glide path preparation using both methods. Glide path enlargement time was significantly shorter with HyFlex EDM GPF (27.828 ± 2.345 sec) than with PathFile (48.942 ± 2.864 sec) (ANOVA, $P < 0.001$).

There was no severe pain in both groups during the first week after the procedure. The highest postoperative pain score was recorded on the first day. All of the patients had mild or moderate pain on the first day, but the pain decreased over time in both groups (Table 3).

The horizontal axis for VAS was the recorded time, which was recorded twice daily (morning and evening) for 1 week after root canal preparation. The vertical axis consisted of the mean VAS scores. HyFlex EDM GPF group patients reported significantly less postoperative pain than PathFile group patients overall, with a significant P value of less than 0.05 (Figure 1).

The results of the repeated measurement ANOVA model showed that the Mauchly sphericity test was statistically significant ($P < 0.001$). There were statistically significant differences in pain scores between the HyFlex EDM GPF group and the PathFile group ($F = 8.336$, $P = 0.005$). There were statistically significant differences in pain scores at 14 different times after root canal instrumentation ($F = 119.191$, $P < 0.001$). The pain scores for the HyFlex EDM GPF group and the PathFile group showed the same trend at 14 time points ($F = 0.981$, $P = 0.479$).

Discussion

This randomized clinical trial aimed to compare the HyFlex EDM GPF versus PathFile with regard to the glide path preparation time and postoperative pain. The mean preparation time was significantly shorter with HyFlex EDM GPF than with PathFile. This shorter time can be explained by the fact that two instruments are used in the PathFile system, whereas only a single instrument is used in the HyFlex EDM GPF system. A recent study by Kirchhoff et al. compared glide path preparation using ProGlider and PathFile in curved mandibular canals. The ProGlider is a single-instrument system, whereas the PathFile is a multi-file system. The authors reported that faster glide path preparation was achieved with the single instrument system [12]. Another study also compared the glide path preparation time with the ProGlider file, PathFile, X-Plorer Canal Navigation NiTi file, and stainless-steel K-file [19]. They also reported that there was a significantly shorter preparation time with the ProGlider file compared to the other systems.

Interestingly, the present study found that the time for ProTaper Next preparation was also significantly shorter in the HyFlex EDM GPF group than in the PathFile group as the preliminary enlargement of the root canal at the coronal and middle portions reduced torsional stress during subsequent root canal preparation, and therefore the WL could be achieved more easily with the ProTaper Next. It should also be noted that the larger taper (up to 5%) of the HyFlex EDM GPF creates a larger canal at the coronal and middle portions.

Postoperative pain is considered to have a significant impact on quality of life, thus proper management of the pain is very important. Although postoperative pain is multifactorial, the instrumentation technique is considered to play a major role in the pain [9, 20, 21]. During chemomechanical preparation, infected debris and extruded bacteria may be transported to periapical tissues, where they can induce an acute inflammatory response in the periapical region [22]. In this study, the WL and the type and amount of irrigating solution were controlled as these factors can influence debris extrusion, which may affect the periodontal ligament response. Thus, efforts were made to minimize over-preparation by controlling the WL using an apex locator and radiographic verification in all cases. Irrigant extrusion was limited by using side-vented irrigation needles to deliver the irrigants to the apex safely and effectively. The present

study showed that the significant differences in postoperative pain scores between GPFs and ProTaper Next might be due to the extrusion of debris.

In the present study, the highest postoperative pain score was recorded on the first day. All patients had mild or moderate pain on the first day and the pain decreased over time in both groups. Postoperative pain can occur within a few hours or a few days after endodontic treatment [23]. In systematic reviews, the incidence of postoperative pain was reported to range from 25 to 40% [1, 2] and varied between reports according to the study type (prospective or retrospective), selection of patients, pulp and apical periodontitis diagnosis, and the experience and qualification of the dentist.

Glide path preparation minimizes the debris and bacterial extrusion into the periapical region, which further reduces the postoperative pain regardless of the instrument types used for canal shaping [21, 24]. In the present study, postoperative pain was significantly lower in the HyFlex EDM GPF group compared with that in the PathFile group. The larger taper (up to 5%) of the HyFlex EDM GPF is intended to remove cervical interference from the root canal entrance, providing free access for endodontic instruments and irrigants to the periapical region, which further helps in reducing the extrusion of debris. A study by Ha et al. indicated the progressive taper design of ProGlider, the off-center cross-section of One G, and the alternative-pitch design of ScoutRace are intended to increase the efficiency of debris removal and minimize extrusion during glide path preparation. Debris extrusion is reported to be lower with the ProGlider system than with the PathFile and One G systems [24].

Glide path preparation prior to mechanical enlargement helps in reducing procedural errors during subsequent root canal procedures. Apical transportation and foramen widening may result in the loss of the apical stop, which further causes more postoperative discomfort [25]. In this study, glide path preparation using HyFlex EDM GPF with large taper designs could produce enlargement in the coronal and middle third of the root canal, which will allow subsequently used instruments to more consistently reach the apical foramen and also helps in improving the precision of electronic apex locators for determining the WL.

The HyFlex EDM GPF has significantly greater cyclic fatigue resistance and flexibility than PathFile [15]. The cyclic fatigue resistance for HyFlex EDM was 700% greater than that for HyFlex CM files made of the same alloy. The porous cratered surface of the EDM files was maintained with no change to the cutting blades even after being used in curved root canals [15]. Another study compared the cyclic fatigue resistances amongst different file systems in artificial canals created with HyFlex GPF (Coltene-Whaledent), G Files (Micro-Mega, Besançon, France), ProGlider (Dentsply Sirona), PathFile, and ScoutRaCe (FKG Dentaire, La Chaux-de-Fonds, Switzerland) NiTi rotary GPFs. The authors found that the greatest cyclic fatigue resistance was in HyFlex GPF made of CM alloy [26]. The flexibility and cyclic fatigue resistance of HyFlex EDM GPF confers this instrument the ability to maintain the apical canal curvature despite its greater taper, which may lead to low postoperative pain.

The limitation of this study was that the endodontic dentist was not blinded to the grouping information. Additionally, the type of teeth was not standardized in the study and there was no differentiation between

maxillary and mandibular molars or between first and second molars.

Conclusions

Glide path preparation time is shorter and postoperative pain severity is lower with the HyFlex EDM GPF than with PathFile. Glide path preparation with HyFlex EDM GPF is advantageous to the subsequent NiTi instruments and can reduce postoperative pain. The highest postoperative pain score was recorded on the first day.

Abbreviations

glide path files (GPFs), controlled memory (CM).

Declarations

Ethics approval and consent to participate

Ethical approval was obtained from the Biomedical ethics committee of Stomatological Hospital of Peking University. The committee's reference number is PKUSSIRB-201735063. The informed consent obtained from study participants was written.

Consent for publication

Not Applicable

Availability of data and material

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

XMH and YH designed the study. YH collected and analyzed the data, drafted the manuscript. XMH finalized the manuscript and acted as corresponding author. All authors have read and approved the final

manuscript.

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Not Applicable

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Tables

Table 1. Characteristics of the two groups

Demographic data	HyFlex EDM GPF group	PathFile group	<i>P</i> value*
Age, years	48.1 ± 14.1	45.5 ± 14.4	<i>P</i> >0.05
Male	12	11	
Female	28	29	
First molar	19	19	
Second molar	21	21	
Angle of root canal	28.8° ± 6.8°	26.5° ± 8.3°	
Asymptomatic irreversible pulpitis	9	7	
Symptomatic irreversible pulpitis	31	33	

Data are mean ± standard deviation or number.

**P*>0.05, statistically not significant.

Table 2. Preparation times (in seconds) in the two groups

Group	n	Time for glide path preparation	Time for ProTaper Next preparation	Total time
HyFlex EDM GPF group	40	27.8 ± 2.3	69.4 ± 4.0	97.3 ± 6.0
PathFile group	40	48.9 ± 2.9	73.9 ± 4.5	122.8 ± 6.5
<i>F</i> statistic		1559.66	6.75	333.80
<i>P</i>		<0.001	0.011	<0.001

Values are means ± standard deviations

Table 3 Descriptive statistics of postoperative pain results for HyFlex EDM GPF and PathFile groups

VAS score	Treatment group	Postoperative follow-up interval													
		AM1	PM1	AM2	PM2	AM3	PM3	AM4	PM4	AM5	PM5	AM6	PM6	AM7	PM7
no pain (0)	HyFlex EDM GPF	0	1	1	1	1	1	5	6	10	11	16	16	21	21
	PathFile	0	0	0	0	1	1	1	1	3	3	7	9	14	14
mild pain (1-3)	HyFlex EDM GPF	18	19	28	29	31	34	32	31	28	27	23	23	18	18
	PathFile	13	13	21	23	26	27	28	28	29	29	29	28	25	25
moderate pain (4-6)	HyFlex EDM GPF	22	20	11	10	8	5	3	3	2	2	1	1	1	1
	PathFile	27	27	19	17	13	12	11	11	8	8	4	3	1	1
severe pain (7-10)	HyFlex EDM GPF	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	PathFile	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Figures

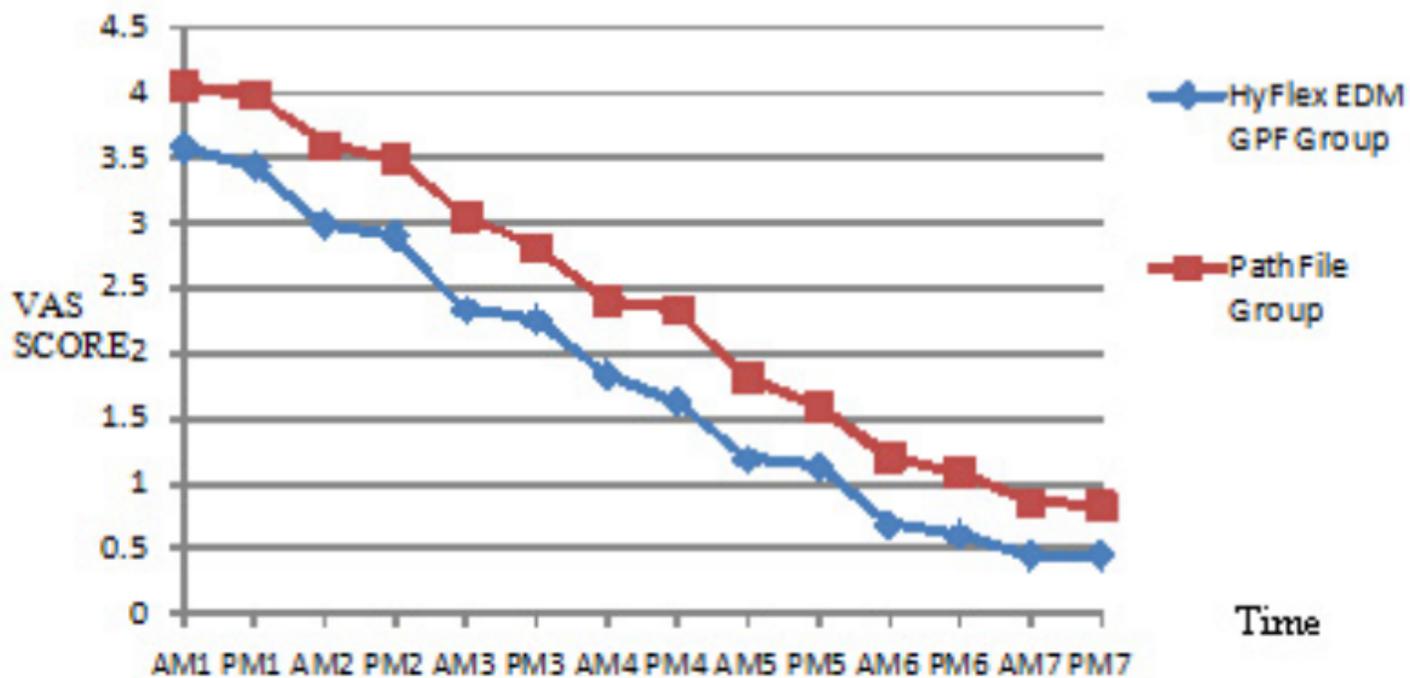


Figure 1

Postoperative VAS scores in the two groups at different time points. The mean preoperative and postoperative VAS scores. HyFlex EDM GPF group patients reported significantly less postoperative pain than PathFile group patients overall, with a significant P value of less than 0.05.

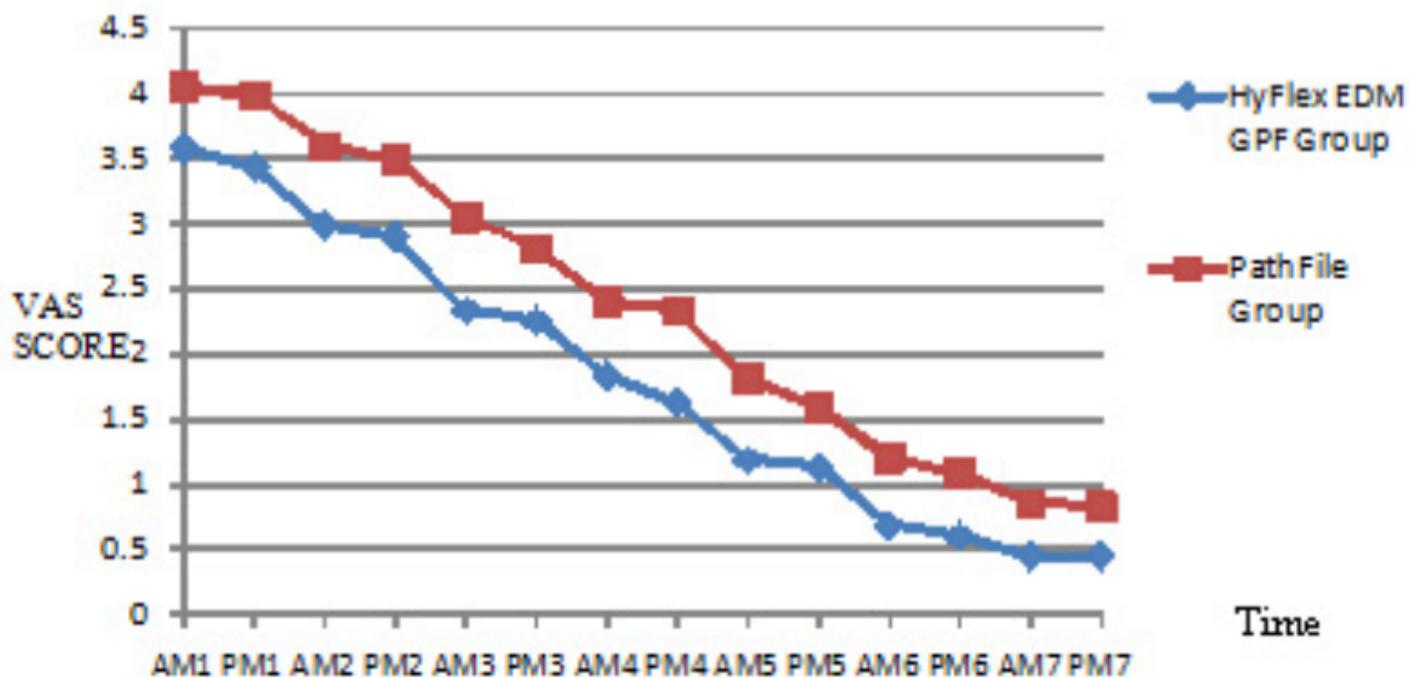


Figure 1

Postoperative VAS scores in the two groups at different time points. The mean preoperative and postoperative VAS scores. HyFlex EDM GPF group patients reported significantly less postoperative pain than PathFile group patients overall, with a significant P value of less than 0.05.

Supplementary Files

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